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09/768,012	01/22/2001	Michael J. McCluskie	C1040/7010	9273

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EXAMINER
NGUYEN, DAVE TRONG

ART UNIT	PAPER NUMBER
1632	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No. 09/768,012	Applicant(s) MCCLUSKIE ET AL.	
	Examiner Dave Nguyen	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31,52,55,78,112,124,135,136,142,150,152 and 153* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-31,52,55,78,112,124,135,136,142,150,152 and 153* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Claims 1-31, 52, 55, 78, 100, 112, 124, 142, 150, 152, 153, are pending.

Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-31, 52, 100, embracing a composition comprising a Th2-immunstimulatory nucleic acid and an antigen, and method using the composition for inducing an antigen specific response, classifiable in class 530, subclass 806.

II. Claims 55, drawn to a method for treating a non-autoimmune Th1-mediated disease, comprising:

Administering to a subject a Th2 immunostimulatory nucleic acid when administered mucosally or dermally, classifiable in class 514, subclass 44.

III. Claims 78, drawn to a method for treating an autoimmune disease, comprising:

Administering to a subject a Th2 immunostimulatory nucleic acid when administered mucosally or dermally, wherein the subject has not been exposed to a Th1 immunostimulatory nucleic acid, classifiable in class 514, subclass 44.

IV. Claim 112, drawn to a pharmaceutical composition comprising an effective amount of a Th2 immunostimulatory nucleic acid and an adjuvant, classifiable in class 514, subclass 44.

V. Claim 124, drawn to a method of treating an infectious disease in a subject, comprising:

Administering to a subject having any infectious disease a Th2 immunostimulatory nucleic acid when administered mucosally or dermally, wherein the subject has not been exposed to a Th1 immunostimulatory nucleic acid, classifiable in class 514, subclass 44.

VI. Claims 142, 150, drawn to a pharmaceutical composition comprising: A Th2 immunostimulatory nucleic acid in an effective amount for inducing ADCC, a monoclononal antibody, and a pharmaceutically acceptable carrier, classified in class 530, subclass 390.1.

VII. Claims 152, 153, drawn to a composition comprising a Th2 immunostimulatory nucleic acid having a phosphodiester backbone, formulated in a delivery vehicle selected from the group consisting of bioadhesive polymers, enteric coated capsules, microspheres, nanospheres, and polymer rings, classifiable in class 424, subclass 468.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to <u>different</u> methods, restriction is deemed to be proper because these methods constitute patentably distinct inventions for the following reasons: Inventions I to XII are directed to different goals and comprises materially distinct steps. The materials and method steps in each of the invention comprise distinct product and steps, respectively, in order to generate a end result as intended by the preamble of each of the elected invention. For example, the use of antigens is not equivalent to that of antibody, nor is equivalent to the use of solely Th2 immunostimulatory nucleic acid. Treatment of any infectious disease is neither equivalent to treatment of an autoimmune disease nor a Th1 mediated non-auto immune disease. In addition, the composition of Group IV is not limited to use in treatment of an infectious disease and can be used in other inventions as listed above. Furthermore, the combination of an antigen and a Th2-immunostimulatory nucleic acid does not require a delivery vehicle as recited in Group VII, and the composition of Group

VII is not limited for use in Invention I, for example, and can have use in other inventions as listed above. Likewise, the composition of invention VI does not require the adjuvant as recited in Invention IV and the composition of Invention IV and have use in other inventions as listed above. Thus, each of the Inventions I to VII requires distinct prior art search and consideration of patentability with respect to the state of the prior art as a whole.

Should any of the method cited in inventions I-III, V-VI be elected, the claims of the elected invention are generic to a plurality of disclosed patentably distinct species comprising:

Mucosal administration, dermal administration, or parenteral administration.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as specified above, even though this requirement is traversed.

Should applicant elect the parenteral administration, applicant is further required to elect a particular route that is embraced by the parenteral route, *e.g.,* a specifically name route other than through the digestive tract.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should any of the method cited in inventions I-III, V-VI be elected, and should mucosal route be elected, the claims of the elected invention are generic to a plurality of disclosed patentably distinct species comprising:

Eye, mouth, or skin as targeted delivery site.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as specified above, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should Invention I be elected, the claims of the elected invention are further generic to a plurality of disclosed patentably distinct species comprising:

A specifically named therapeutic agent as listed in claim 8 (Th1 adjuvant).

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as specified above, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should Invention I be elected, and should the species of Th1 adjuvant be elected, the claims of the elected invention are further generic to a plurality of disclosed patentably distinct species comprising:

A specifically named Th2 adjuvant as listed in claim 11.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as specified above, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should Invention I, the species of Th1 adjuvant, and the species of Th2 adjuvant from

claim 11 be elected, the claims of the elected invention are further generic to a plurality of disclosed patentably distinct species comprising:

A specifically named Th2 adjuvant as listed in claims 12-15 that also corresponds to the elected species of the Th2 adjuvant from claim 11.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as specified above, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should Invention I be elected, the claims of the elected invention are further generic to a plurality of disclosed patentably distinct species comprising:

A specifically named formulation as recited in claim 17.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as specified above, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should Invention I be elected, and should the targeted site of delivery be elected (see claim 5), the claims of the elected invention are further generic to a plurality of disclosed patentably distinct species comprising:

A specifically named route as listed in claims 18 and 19 and would also correspond to the elected species of targeted delivery site.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as specified above, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should Invention I be elected, the claims of the elected invention are further generic to a plurality of disclosed patentably distinct species comprising:

A specifically named antigen specific immune response as listed in claim 21.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as specified above, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should Invention I be elected, the claims of the elected invention are further generic to a plurality of disclosed patentably distinct species comprising:

A specifically named delivery system for delivering the Th2-immunostimulatory nucleic acid as listed in claim 22.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as specified above, even though this requirement is traversed.

Should Invention I be elected, the claims of the elected invention are further generic to a plurality of disclosed patentably distinct species comprising:

A specifically named delivery system for delivering the antigen as listed in claim 23.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as specified above, even though this requirement is traversed.

Should Invention I be elected, and should the therapeutic agent as Th1 or Th2 adjuvant has not been elected, the claims of the elected invention are further generic to a plurality of disclosed patentably distinct species comprising:

A specifically named therapeutic agent as listed in claim 24.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as specified above, even though this requirement is traversed.

Should Invention I be elected, the claims of the elected invention are further generic to a plurality of disclosed patentably distinct species comprising:

A specifically named antigen as listed in claim 25.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as specified above, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory

classes of invention, are separately classified and searched, and establish an unduly search burden, a restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst Dianiece Jacobs, whose telephone number is **(703) 305-3388.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051.**

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is **(703) 305-7401**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen
Primary Examiner
Art Unit: 1632

DAVE T. NGUYEN
PRIMARY EXAMINER